

claims 13 and 14, as originally filed. The claims as amended also find basis throughout the specification.

Proposed amended Figures 14 to 26 have been amended to refer the T-cell and B-cell epitopes to specific SEQ ID NOs, consistent with the amended sequence listing.

Proposed amended Figure 23 has also been amended to correct an obvious error. Figure 23 as originally filed refers to a “possible T-cell epitope” at position 640 of SEQ ID NO:23. There is no position 640 because SEQ ID NO:23 is only 514 amino acids long. Moreover, the sequence of the “possible T-cell epitope” does not occur anywhere in SEQ ID NO:23.

Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Election in Response to the Restriction Requirement

In response to the Restriction Requirement mailed October 4, 2002, Applicants hereby elect the claims of Group II (claims 1-19, 25 and 36), drawn to DNA, vector, host cells, and a method of preventing infection, for prosecution in the subject application, **with traverse**.

In response to the unity-of-invention requirement, Applicants elect the invention relating to SEQ ID NOs: 1 and 14 (nucleic acid and amino acid sequences of the polypeptide identified as CPN100686 RY-54, a putative 98kDa outer membrane protein) for prosecution. SEQ ID No: 14 is the amino acid sequence of CPN100686, a putative 98kDa outer membrane protein. SEQ ID No: 1 is a nucleic acid sequence encoding SEQ ID No: 14. The claims readable on the elected invention are claims 1-39, as amended below.

The Examiner has alleged that the claims of Groups I-V do not relate to a single inventive concept under PCT Rule 13.1. Applicants respectfully disagree.

**A. The DNA and the polypeptide have
the same essential structural element**

Applicants maintain that the polypeptide of SEQ ID No: 14 and a nucleic acid encoding it constitute a single inventive concept. Annex B of the Administrative Instructions Under the PCT describes three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in detail. One particular situation describes the relationship between intermediate and final products, as follows:

(g) Intermediate and Final Product. The situation involving intermediate and final products is also governed by Rule 13.2.

(i) The term "intermediate" is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products having the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(ii) Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural elements, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

A nucleic acid and the polypeptide it encodes are starting products and final products. There is unity because the DNA and the polypeptide have the same essential structural element, namely that both products share the same polymeric sequence. While nucleic acids and polypeptides are chemically different, the claimed nucleic acids and polypeptides share the same sequence structure, since the initiator codon is described and the nucleic acid sequence is understood to be read in triplets. Applicants draw the Examiner's attention to part (f)(ii) of the Administrative

Instructions, which states that “the structural element may be a single component or a combination of individual components linked together”.

B. Example 17 of Annex B states that there is unity between protein and DNA

The Examiner is directed to Example 17 of Annex B of the Administrative Instructions Under the PCT. Example 17 states that there is unity between a claim to protein X and a claim to DNA sequence encoding protein X because the protein and the DNA sequence exhibit corresponding special technical features.

In consideration of the above, Applicants submit that the claims of Group I (claims 20-24 and 27-34) and Group II (claims 1-19, 25 and 36) should be joined.

C. The polypeptide and its corresponding antibody share a special technical feature

The Examiner is directed to Example 8 of Annex B of the Administrative Instructions Under the PCT. Example 8 states that there is a special technical feature included in a claim to a plug characterized by feature A and a claim to a socket characterized by corresponding feature A, and that there is unity between these claims. The correspondence between a plug and its socket is equivalent to the correspondence between a protein and an antibody binding to it.

In consideration of the above, Applicants submit that the claims of Group II (claims 1-19, 25 and 36) and Group III (claims 26 and 35) should be joined.

D. The protein/DNA, methods of manufacturing them and methods of using them share a special technical feature

The Examiner is directed to Example 1 of Annex B of the Administrative Instructions Under the PCT. Example 1 states that there is a special technical feature (substance X) between three categories of claims: (a) a claim to substance X; (b) a claim to a method of manufacturing substance X; and (c) a claim to the use of substance X, and states that the claims therefore have unity.

The claims of Groups IV and V (claims 37-39) are drawn to specific uses of the protein and DNA. The protein/DNA is the special technical feature between these claims and the claims of Groups I and II. Applicants submit that the claims of Groups IV and V (claims 37-39), and the claims of Groups I and II (claims 1-19, 20-34 and 36) should be joined.

E. Burden of search

It is respectfully submitted that by this Amendment, the subject matter of the claims is sufficiently related that a thorough search of the subject matter of any one single independent claim would necessarily encompass a search for the subject matter of the remaining claims.

Thus, it is respectfully submitted that the search and examination of the entire application could be performed without serious burden. MPEP §803 clearly states that “If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” (emphasis added). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants in duplicative examination by the Patent Office.

III. Concluding remarks

The Examiner is respectfully requested to reconsider and withdraw the Restriction Requirement and to examine all the claims now pending in this application.

In accordance with this election with traverse, applicants reserve all rights in the non-elected claims, including the right to file one or more divisional applications covering the subject matter thereof.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of:
 - (d) ~~SEQ ID Nos: 15 to 26~~SEQ ID No: 14;
 - (e) an immunogenic fragment comprising at least ~~42~~50 consecutive amino acids from a polypeptide of (a); and
 - (f) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. (Amended) A nucleic acid molecule comprising a nucleic acid sequence selected from any one of:
 - (f) ~~SEQ ID Nos: 2 to 13~~SEQ ID No: 1;
 - (g) a sequence which encodes a polypeptide encoded by ~~any one of SEQ ID Nos: 2 to 13~~SEQ ID No: 1;
 - (h) a sequence comprising at least 38 consecutive nucleotides from ~~any one of the nucleic acid sequences of (a) and (b)~~ SEQ ID No: 1; and
 - (i) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to ~~any one of the polypeptides the polypeptide~~ encoded by ~~SEQ ID Nos: 2 to 13~~SEQ ID No: 1; and
 - (j) a sequence comprising at least 100 consecutive nucleotides from a nucleic acid sequence of (b).

8. (Amended) A vaccine comprising a vaccine vector and at least one first nucleic acid selected from any one of:
 - (i) ~~SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
 - (ii) a nucleic acid sequence which encodes a polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;

- (iii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (i) and (ii);
- (iv) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~ SEQ ID No: 1;
- (v) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in ~~any one of SEQ ID Nos: 14 to 26~~ SEQ ID No: 14;
- (vi) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from ~~any one of SEQ ID Nos: 14 to 26~~ SEQ ID No: 14; and
- (vii) a nucleic acid sequence which encodes a polypeptide as defined in (i) to (v) or an immunogenic fragment as defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (v) or the corresponding fragment of (vi);

wherein each first nucleic acid is capable of being expressed.

9. (Amended) A vaccine comprising a vaccine vector and at least one first nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

- (a) a first polypeptide selected from any one of:
 - (i) a polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~ SEQ ID No: 1;
 - (ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from ~~any one of SEQ ID Nos: 1 to 13~~ SEQ ID No: 1;
 - (iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~ SEQ ID No: 1;
 - (iv) a polypeptide whose sequence is set forth in ~~any one of SEQ ID Nos: 14 to 26~~ SEQ ID No: 14;
 - (v) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~any one of SEQ ID Nos: 14 to 26~~ SEQ ID No: 14; and

- (vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and
 - (b) a second polypeptide;
- wherein each first nucleic acid is capable of being expressed.

18. (Amended) An isolated nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to ~~any one of nucleic acid molecules of SEQ ID Nos: 2 to 13~~SEQ ID No: 1, or to a complementary or anti-sense sequence of said nucleic acid molecule.

19. (Amended) An isolated primer of 10 to 40 nucleotides which hybridizes under stringent conditions to ~~any one of nucleic acid molecules of SEQ ID Nos: 2 to 13~~SEQ ID No: 1, or to a complementary or anti-sense sequence of said nucleic acid molecule.

21. (Amended) A polypeptide comprising an amino acid sequence selected from any one of:

- (d) ~~SEQ ID Nos: 15 to 26~~SEQ ID No: 14;
- (e) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and
- (f) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

27. (Amended) A vaccine comprising at least one first polypeptide selected from any one of:

- (i) a polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
- (ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;

- (iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
- (iv) a polypeptide whose sequence is set forth in ~~any one of SEQ ID Nos: 14 to 26~~SEQ ID No: 14;
- (v) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~any one of SEQ ID Nos: 14 to 26~~SEQ ID No: 14; and
- (vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v).

28. (Amended) A vaccine comprising at least one fusion protein, wherein the fusion protein comprises:

- (a) a first polypeptide selected from any one of:
 - (i) a polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
 - (ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
 - (iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by ~~any one of SEQ ID Nos: 1 to 13~~SEQ ID No: 1;
 - (iv) a polypeptide whose sequence is set forth in ~~any one of SEQ ID Nos: 14 to 26~~SEQ ID No: 14;
 - (v) an immunogenic fragment comprising at least 12 consecutive amino acids from ~~any one of SEQ ID Nos: 14 to 26~~SEQ ID No: 14; and
 - (vi) a polypeptide as defined in (i) to (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (i) to (iv) or the corresponding fragment of (v); and
- (b) a second polypeptide.